

REMARKS

As a preliminary matter, Applicants note with appreciation that the Examiner has approved the correction to Figure 2A filed with the Amendment dated April 25, 2002. Applicants further note with appreciation the Examiner's acknowledged consideration of the references listed on Sheet 5 of Form PTO-1449, which were also filed with the Amendment dated April 25, 2002.

Applicants appreciate the withdrawal of the rejection of claim 60 based on anticipation by U.S. Patent 4,994,071 (MacGregor). Applicants also appreciate the withdrawal of the rejection of claims 54-57 and 59-60 based on anticipation by WO 93/13825 (Maeda et al.).

Applicants further appreciate the Examiner's acknowledgement of priority under 35 U.S.C. § 119 and indication that all of the certified copies of the priority documents have been received. Finally, Applicants appreciate the Examiner's acknowledgement of the claim for domestic priority under 35 U.S.C. § 120.

Drawings

The drawings stand objected to for not showing the "hoop-like tubular portions", "corrugated portions", "straightened portions", and "generally straight intermediate portions". Though Applicants believe that the drawings do show these features, a proposed correction to FIG. 2A is enclosed.

An embodiment of the "hoop-like tubular portions" is described in the specification at page 23, line 11 through page 24, line 19, and is shown as a "hoop" or "hoops" 20, 20a, 20b, 25 in FIG. 2A, for example. At page 23, lines 18-20 of the specification, an embodiment of a "corrugated portion" is described, with reference to FIG. 2A, as the part of the wire that "follows a sinuous path to define a plurality of circumferentially spaced apices 22."

An embodiment of a "straightened extension portion" is described, also with reference to FIG. 2A, as "... the point of winding of the nitinol wire is displaced longitudinally with respect to the axis of mandrel 46 to form the next successive hoop 20b" (see page 9, lines 19-24 and page 23, lines 24-27 of the specification). The "straightened extension portions" are shown in the embodiments illustrated in

FIG. 2A, for example, as the parts or portions of the wires that give the appearance of double-lines extending between adjacent "hoop-like tubular portions."

The "generally straight intermediate portions" are the parts or portions of the wire embodiment illustrated in FIG. 2A that connect the apices with one another along a sinuous path.

Though Applicants respectfully submit that the foregoing comments confirm that the cited features are in fact shown in the drawings, a proposed correction to FIG. 2A is enclosed. Embodiments of "hoop-like tubular portions" are already shown at 20, 20a, 20b, and 25. New annotations on FIG. 2A identify exemplary embodiments of a "corrugated portion," a "straightened extension portion" and a "generally straight intermediate portion." Though not deemed necessary by Applicants, at the Examiner's request, FIG. 2A can be further corrected (with corresponding amendments to the specification) to add reference numerals for a "corrugated portion," a "straightened extension portion" and a "generally straight intermediate portion."

Based on the foregoing comments and the proposed correction to FIG. 2A, Applicants respectfully request withdrawal of the objection to the drawings.

Rejections Under 35 U.S.C. § 112, First Paragraph

In the Office Action, claims 54-60 stand rejected under 35 U.S.C. § 112, first paragraph. The Office Action stated that "hoop-like tubular portions," "corrugated portions," "straightened portions", and "generally straight intermediate portions" were not described in the specification. The applicants believe that the specification, together with the drawings, clearly describe these exemplary features. As requested in the Office Action, specific citations to Applicants' specification are provided here:

"hoop-like tubular portions" (see, e.g., FIGS. 1A-4A and Applicants' specification at page 23, line 11 through page 24, line 19 ("hoop" or "hoops" 20, 20a, 20b, and 25));

"corrugated portion" (see, e.g., Applicants' specification at page 23, lines 18-20 (part of the wire that "follows a sinuous path to define a plurality of circumferentially spaced apices 22"));

"straightened extension portion" (see, e.g., FIGS. 2A, 3 and 4A, and Applicants' specification at page 9, lines 19-24 and page 23, lines 24-27 ("... the point of winding of the nitinol wire is displaced longitudinally with respect to the axis of mandrel 46 to form the next successive hoop 20b")); and

"generally straight intermediate portions" (see, e.g., FIGS. 1A-4A and 5-7 (the parts or portions of the wire that connect the apices with one another to form a sinuous path)).

For the foregoing reasons, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Prior Art Rejections

Pending claims 54-61 stand rejected based on MacGregor, Maeda, or a hypothetical combination of MacGregor with Maeda. Each of pending claims 54-61 is discussed below.

Claim 54

Claim 54 recites a generally tubular prosthesis having, among other features, at least two hoop-like tubular portions that are axially arranged generally adjacent to one another. For example, the embodiment of Applicants' tubular prosthesis illustrated in Figure 2A includes hoop-like tubular portions 20 that are axially arranged generally adjacent to one another. The tubular portions 20 are proximal to one another as at the location labeled 21 in Figure 2A, and the tubular portions 20 optionally contact one another. Accordingly, the hoop-like tubular portions axially arranged "generally adjacent to one another," as recited in claim 54, are proximal to one another.

Claim 54 stands rejected as anticipated by MacGregor. Specifically, the Office Action cited Figure 1A of MacGregor as showing that "at least two of said

hoop-like tubular portions are axially arranged generally adjacent to one another." Applicants respectfully disagree.

Figure 1A of MacGregor shows loops 12 that are separated by at least a loop's axial width. In other words, the gap interposed to separate successive loops 12 is larger than the axial width of the loops themselves. Such a configuration cannot be considered to constitute "hoop-like tubular portions . . . axially arranged generally adjacent to one another" as recited in Applicants' claim 54. Accordingly, MacGregor fails to anticipate claim 54.

The Office Action fails to cite any disclosure in MacGregor of hoop-like tubular portions that are "axially arranged generally adjacent to one another." Accordingly, withdrawal of the rejection of claim 54 based on MacGregor is respectfully requested.

Claim 55

Claim 55 recites that the corrugations of the stent comprise zig-zags having V-shaped apices connected by generally straight intermediate portions. For example, the embodiment of Applicants' tubular prosthesis illustrated in Figure 2A includes corrugations having zig-zags with V-shaped apices 22 that are connected to one another by generally straight intermediate portions that extend between the apices 22.

Claim 55 stands rejected as being anticipated by MacGregor. This rejection, however, explicitly requires a modification to the structure disclosed in the MacGregor reference from the U-shaped form taught by MacGregor to the V-shaped form claimed by Applicants in claim 55. Specifically, Paragraph 6 of the Office Action includes the statement: "Regarding claim 55, it should be noted that the apices, although of U-shaped form, could be *modified* into V-shaped form (well known in the art) without departing from the spirit of the invention." Accordingly, it is respectfully submitted that MacGregor fails to anticipate or even suggest this feature recited in Applicants' claim 55.

The Office Action fails to cite any disclosure in MacGregor of Applicants' claimed V-shaped zig-zag configuration. Accordingly, it is respectfully submitted that the rejection of claim 55 as anticipated by MacGregor must be withdrawn.

Claim 56

Claim 56 recites a tubular prosthesis having at least some straightened extension portions oriented skew relative to the tubular axis of the prosthesis. Referring to annotated Figure 2A (enclosed), one embodiment of Applicants' tubular prosthesis includes extension portions that are skew with respect to the axis of the tubular prosthesis.

Claim 56 stands rejected as anticipated by MacGregor. More specifically, the Office Action cites Figure 1A of MacGregor as showing "straightened extension portions slightly oriented skew relative to the tubular axis." Applicants respectfully disagree.

Figure 1A of MacGregor, cited by the Examiner, fails to disclose any extension portion oriented skew relative to the tubular axis. In fact, MacGregor explicitly teaches wire portions that extend axially along the length of the prosthesis. Specifically, at column 3, lines 56-58, MacGregor teaches "loops 12 interconnected by a sequence of half-hitch connections 14 (Fig. 1A) which extend along an axial dimension." Also, at column 4, lines 6-8, MacGregor teaches that the "wire 26 forms a backbone 28 extending axially along the length of the lattice 16."

Accordingly, MacGregor fails to anticipate the "skew" orientation recited in Applicant's claim 56. Instead, MacGregor teaches away from that feature by teaching an axial orientation. Accordingly, withdrawal of the rejection of claim 56 based on MacGregor is respectfully requested.

Claim 57

Claim 57 recites a tubular prosthesis having, among other features, tubular portions that are arranged generally adjacent to each other. As described previously in connection with claim 54, and referring to Applicants' Figure 2A for illustration, tubular portions 20 are arranged generally adjacent to each other in that they are positioned proximal to one another.

For the same reasons set forth in connection with claim 54, MacGregor fails to anticipate claim 57. Accordingly, it is respectfully submitted that the rejection of claim 57 as anticipated by MacGregor should be withdrawn.

Claim 58

Dependent claim 58 incorporates all of the features of independent claim 54 and further recites that the prosthesis is a forked prosthesis comprising a generally tubular main branch and at least two secondary branches extending from the main branch.

Claim 58 stands rejected as anticipated by MacGregor. It is respectfully submitted that, for the same reasons set forth in connection with claim 54, MacGregor fails to anticipate claim 58 because claim 58 recites hoop-like tubular portions that are axially arranged generally adjacent to one another. Withdrawal of the rejection of claim 58 is respectfully requested.

Claim 59

Claim 59 is amended to recite a tubular prosthesis comprising, among other features, one or more corrugated portions having zig-zags with V-shaped apices connected by generally straight intermediate portions. The prosthesis also includes one or more generally straightened extension portions extending between and connecting consecutive hoop-like tubular portions, wherein the straightened extension portion is oriented skew relative to the tube axis and extends in a substantially helical path. Consecutive hoop-like tubular portions are connected at a point circumferentially displaced from the extension portion.

Claim 59 stands rejected as anticipated by MacGregor. It is respectfully submitted that MacGregor fails to disclose the features now recited in amended claim 59. Specifically, and as acknowledged in the Office Action in connection with claim 60, MacGregor fails to disclose or suggest (and teaches away from) a straightened extension portion oriented skew relative to the tube axis and extending in a substantially helical path. MacGregor also fails to disclose or suggest one or more corrugated portions having zig-zags with V-shaped apices connected by generally straight intermediate portions. Accordingly, withdrawal of the rejection of claim 59 is respectfully requested.

Claim 60

Claim 60 recites a tubular prosthesis having, among other features, a plurality of wires or filaments each having one or more corrugated portions. Claim 60 further recites that at least one of the wires or filaments has one or more generally straightened extension portions that extend in a helical path between and connect consecutive hoop-like tubular portions. Referring to Applicants' Figure 2A, one embodiment of the extension portions extends in a helical path with respect to the axis of the tubular prosthesis.

Claim 60 stands rejected as being unpatentable over a hypothetical combination of MacGregor with Maeda. The Office Action acknowledges that MacGregor fails to disclose extension portions extending in a helical path. Maeda is introduced to provide this missing element of MacGregor. Specifically, the Office Action cites the passages of Maeda found at page 3, lines 16-18 and page 5, lines 16-29.

Page 3, lines 16-18 of Maeda simply recites that "[o]ne object of the present invention is to provide an elongated self-expanding stent having substantially uniform expansile force along the length of the stent." Page 5, lines 16-29 of Maeda recites that "[t]he construction of the stent is completed by helically winding elongated zigzag pattern 5 about a central axis 31." That passage further recites that "Zigzag pattern 5 is wound in such a way that a majority of the bends 8 are distributed in a helix along the length of the stent 30."

Based on the foregoing passages cited in the Office Action, Maeda fails to suggest that the wire should include extension portions, helical or not, that connect consecutive hoop-like tubular portions. Instead, Maeda simply discloses a zigzag pattern 5 that is helically wound about a central axis 31 such that a majority of the bends 8 are distributed in a helix along the length of the stent 30. In other words, Maeda suggests orienting the zigzag pattern 5 along a helical path to form a tubular stent. By helically winding its zigzag pattern 5 (so that bends 8 are distributed in a helix), Maeda has eliminated any need for extension portions.

Because Maeda teaches a helically wound zigzag pattern 5, Maeda fails to suggest the use of a generally straightened extension portion for the connection of

consecutive tubular portions. Accordingly, even the hypothetical combination of MacGregor with Maeda fails to set forth a *prima facie* case of obviousness. Withdrawal of the rejection of claim 60 based on MacGregor in view of Maeda is respectfully requested.

Claim 61

Claim 61 recites an endoluminal stent having, among other features, hoops including a plurality of sinuous or zig-zag segments having apices in a plane substantially perpendicular to the longitudinal axis of the stent. Claim 61 further recites that adjacent hoops are connected by a connecting segment that extends along a helical path from one adjacent hoop to another.

Claim 61 stands rejected as being anticipated by MacGregor. Specifically, the Office Action cites Figures 1 and 1A of MacGregor.

It is respectfully submitted that MacGregor fails to anticipate claim 61 in that the cited Figures 1 and 1A fail to disclose or suggest a connecting segment that extends along a helical path from one adjacent hoop to another, as recited in claim 61. This deficiency of MacGregor was explicitly acknowledged in the Office Action in connection with claim 60. In fact, as mentioned previously in connection with claim 56, MacGregor teaches away from a helical connecting segment by teaching an axial orientation. Accordingly, MacGregor fails to anticipate claim 61.

Claim 61 also stands rejected as being anticipated by Maeda. Reference is made in the Office Action to the Abstract; page 5, lines 23-33; page 6, lines 13-16 and 25-27; page 9, lines 11-16; and Figures 1, 3 and 6. Upon review of those passages and figures, it is clear that Maeda fails to disclose or suggest an endoluminal stent in which each of the hoops has apices in a plane substantially perpendicular to the longitudinal axis of the stent, as recited in claim 61. In fact, Maeda teaches away from that claimed feature of Applicants' invention. Specifically, at page 5, lines 26-29, Maeda teaches that the zigzag pattern 5 should be wound in such a way that a majority of the bends 8 are distributed in a helix along the length of the stent 30. If all of Maeda's bends 8 were oriented in planes perpendicular to the tube's axis, the Maeda zigzag pattern 5 would not progress along the length of the stent.

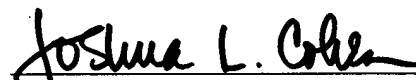
Although Maeda discloses that, by providing gradually increasing length wire sections on either end of the zigzag pattern, the final stent can have a tubular shape in which the ends of the tube are substantially perpendicular to the central axis of the stent (at page 6, lines 27-29), there is no suggestion in Maeda that *each* of the hoops has perpendicular apices. In fact, Maeda specifically teaches away from such a structure.

For the foregoing reasons, it is respectfully submitted that the rejection of claim 61 as anticipated by MacGregor or Maeda should be withdrawn.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections of claims 54-61 based on MacGregor, Maeda, or a hypothetical combination of MacGregor with Maeda should be withdrawn. Based on the amendment to claim 59 and the remarks in this response, it is respectfully submitted that this application is now in form for allowance. A Notice of Allowance is respectfully requested.

Respectfully submitted,



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Enclosure: Version with markings to show changes made
Proposed Correction to Fig. 2A

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December 10, 2002

Joshua L. Cohen

VERSION WITH MARKINGS TO SHOW CHANGES MADE

59. (Amended) A generally tubular prosthesis [for implantation in a human or animal duct to ensure a passageway in said duct, said prosthesis] having [a tubular surface and] a tube axis and [being generally axially subdivided into] two or more [circumferentially oriented] hoop-like tubular portions, said prosthesis comprising:

one or more [a plurality of discrete structural] wires or filaments [joined together to form said prosthesis, said wires or filaments] each having one or more corrugated portions and [at least some of said wires or filaments having] one or more generally straightened extension portions,

[wherein said hoop-like tubular portions are formed from said corrugated portions of two or more of said wires or filaments,]

wherein said corrugated portion comprises zig-zags having V-shaped apices connected by generally straight intermediate portions,

wherein said straightened extension portion[s] extends between and connects consecutive ones of said hoop-like tubular portions, said straightened extension portion being oriented skew relative to said tube axis and extending in a substantially helical path, and

wherein consecutive ones of said hoop-like tubular portions are also connected at a point circumferentially displaced from said extension portion.



2/23

FIG. 2A

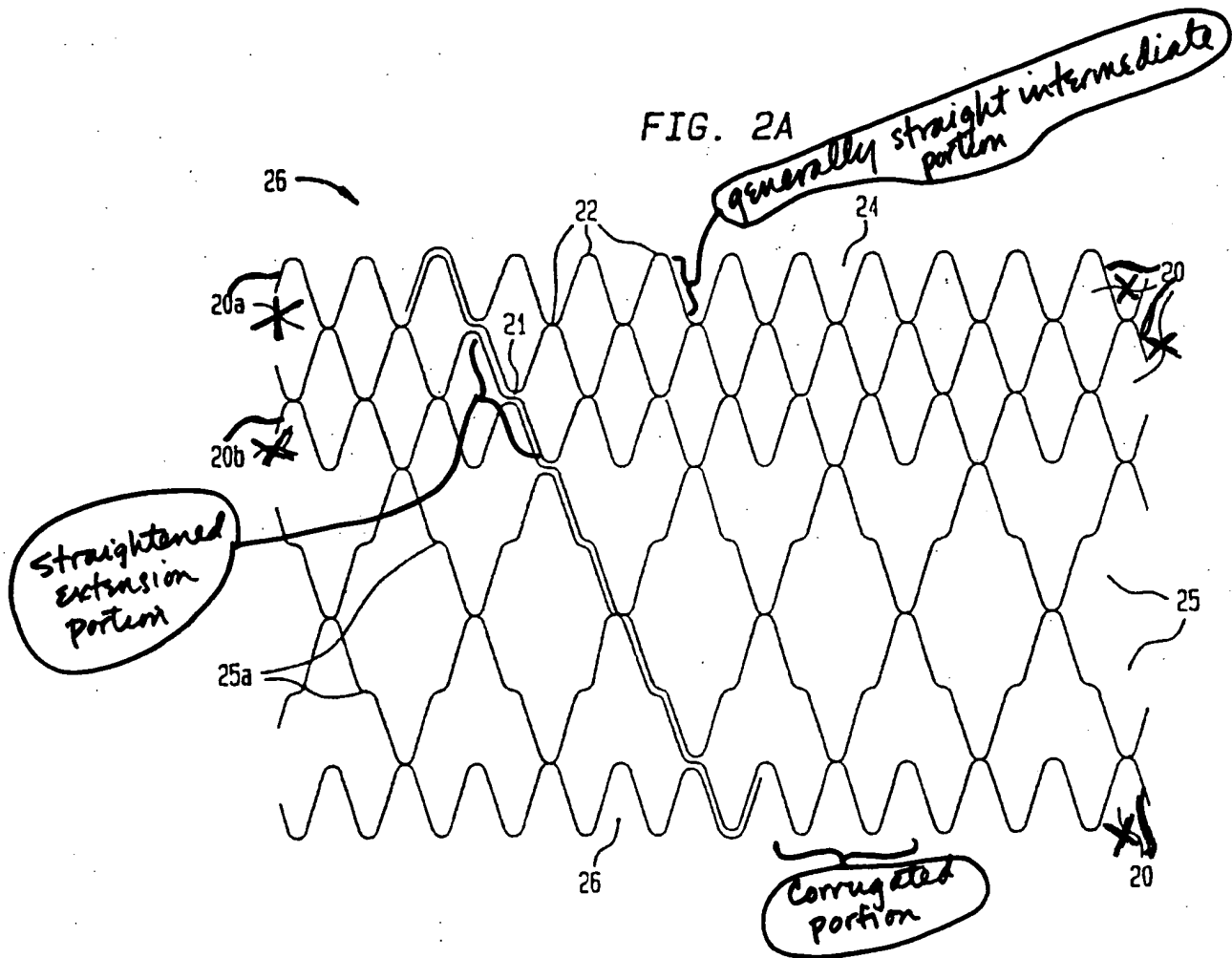
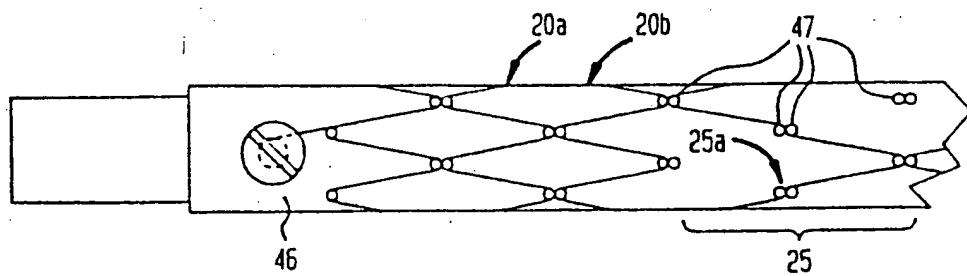


FIG. 2B



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